

Implantable Device Industry Perspective on Fixed Parameter Modes

Partnering for Safe MRI Access

This is a joint presentation from several active implantable medical device manufacturers in the JWG

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MORE CONTROL. LESS RISK.



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Overview

- Shared Patients, Shared Need
 - Goal: Safe MRI access for patients with implantable devices
- Existing MRI safety regulations limit exposure fields based on human physiologic response. Each MRI manufacturer uses proprietary algorithms to adhere to these limits.
- The resulting uncertainty in field levels makes device testing and regulatory approvals very challenging
- Proposed solution: Develop industry wide scanner modes that limit EM field levels to well defined values.
- JWG and MT40 are discussing establishing fixed modes
- AIMD community requests input and support from FDA, MRI Technologists, Radiologists, and MRI Manufacturers

Motivation for MRI Access: Patient and Clinical Perspective

- Increasing patient population with IMDs
 - Passive: hip/knee replacements, stents, heart valves, etc.
 - Active: pacemakers/defibrillators, neurostimulators, drug pumps, etc.
- Increasing diagnostic indications with MRI as gold standard
 - Many IMD patients have MRI on pathway to implant
 - Majority of IMD patients will later need MRI
- Scanning patients with MR Conditional IMDs
 - Scanning an MRI conditional patient is complex
 - Fixed parameter modes will help this issue

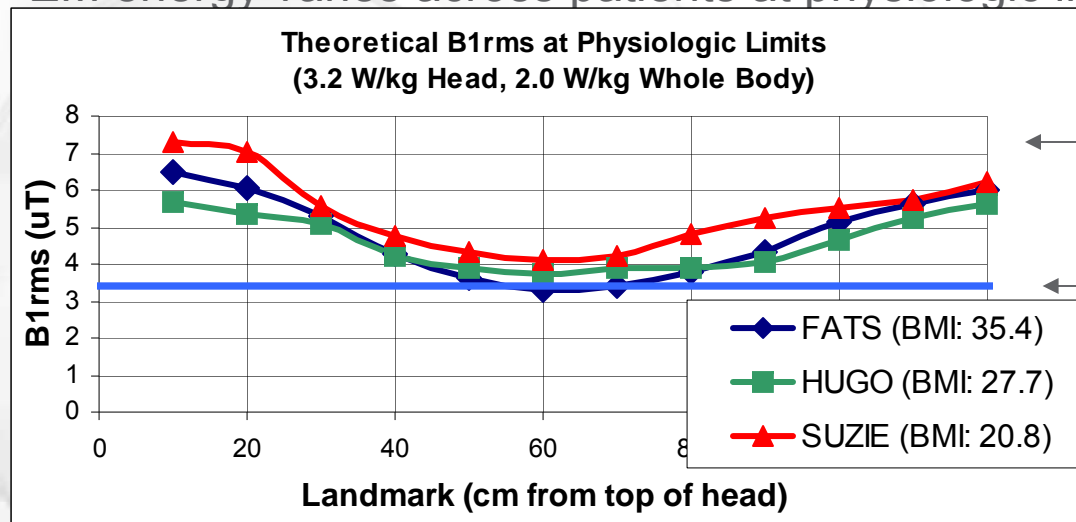
**More
Patients,
Living
Longer**

**Increasing
Value of
MRI Exams**

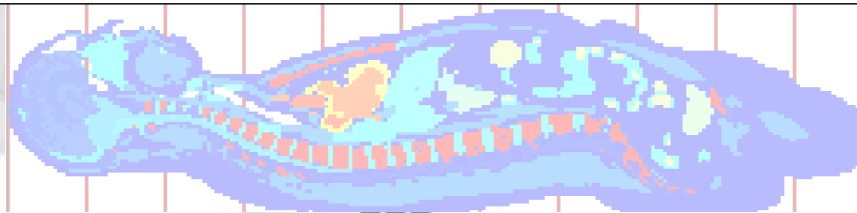
**Patient
Pathway to
MRI**

Physiologic MRI limits

- Existing limits focus on physiologic response but do not directly limit the EM energy within the MRI
 - SAR (W/kg)
 - PNS threshold (% of patient threshold)
- EM energy varies across patients at physiologic limits



$(\text{Max/Min})^2 =$
factor of 4 in
heating



Need for Fixed EM Modes

- Existing limits are implemented using **inconsistent and proprietary methods** across MRI manufacturers
- Presents significant testing and labeling challenges for AIMD manufacturers and regulators
 - Must determine each MR manufacturers implementation
 - MR manufacturers can change implementation over time
 - May force evaluation at extreme non-clinical levels
 - Potentially requires more MRI conditions in labeling
- Fixed modes add clarity to the levels at which devices are to be tested

Device-Critical Parameters

- AIMD agreed device-critical EM parameters on which to standardize MRI output

| EM Parameters | Potential Hazard |
|---|----------------------------|
| Peak RF power (B_{1peak} uT) | Device Damage/EMI |
| Average RF power ($B1_{rms}$ uT) | Lead Heating |
| Peak gradient switching fields (dB/dt_{peak} T/s) | Unintended Stimulation/EMI |
| Average gradient switch fields (dB/dt_{rms} T/s) | Device Heating |

Fixed Parameter Mode(s)

- Defines environment
- Enables:
 - Accurate device characterization
 - Streamlined and consistent approval by regulators
 - Increased MRI access
- Defines a consistent implementation across MR systems

JWG Progress

- Collaboration of AIMD, MRI, regulatory, and academia members
 - Goal: Improve AIMD MRI testing and labeling
- Completed 1st edition of ISO/TS 10974
 - Standardize and improve AIMD/MRI testing, assuming field levels are known
- JWG AIMD participants submitted proposal of fixed modes to MT40
 - Short term: Single mode for 1.5T
 - Long term: Multiple modes for 1.5T and 3T
- Status: MT40 is considering single mode for 1.5T
 - Refined and agreed upon B1rms and B1peak
 - Discussing dB/dt levels
 - We acknowledge that this may require a substantial amount of work by MRI manufacturers
- We ask for support and input to the fixed modes from the FDA, MRI Technologists, Radiologists, MRI Manufacturers

1.5T Fixed Parameter Values in Discussion with MT40

| EM Parameters | Parameter Values |
|--|------------------|
| Peak RF power ($B_{1\text{peak}}$ uT) | 30 uT |
| Average RF power ($B_{1\text{rms}}$ uT) | 3.2 uT |
| Peak gradient switching fields (dB/dt_{peak} T/s) | 80 T/s |
| Average gradient switch fields (dB/dt_{rms} T/s) | 56 T/s |

- This set of parameters provides fixed limits with MR performance near Normal Operating Mode
- A similar proposal for 3T was also made

Conclusions

- Current physiologic limits lead to a varying environment that complicate testing and regulatory submissions
- Directly limiting the EM energy provides
 - A defined environment
 - Avenue for simplified testing and labeling
 - Improved access to MR scans
- JWG and MT40 are discussing fixed exposure limits but additional effort is needed to finalize and implement

Acronyms

- AIMD: Active implantable medical device
- EM: Electromagnetic
- JWG: Joint working group
- IEC: International Electrotechnical Commission
- IMD: Implantable medical device
- ISO: International Organization for Standardization
- MR: Magnetic resonance
- MRI: Magnetic resonance imaging
- MT40: IEC subcommittee 62 B maintenance team 40:
Magnetic resonance equipment for medical
diagnosis
- PNS: Peripheral nerve stimulation
- SAR: Specific absorption rate
- TS: Technical specification